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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/989,758	11/20/2001	Todd R. Golub	WIBL-P0L-579	9648

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02/18/2005

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EXAMINER

FREDMAN, JEFFREY NORMAN

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 02/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/989,758

Applicant(s)

GOLUB ET AL.

Examiner

Jeffrey Fredman

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 8, 15-20, 39 and 40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-5, 8, 15-20, 39 and 40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Status

1. This action is NON-FINAL since the new rejections in the action below are not necessitated by Applicant's amendment.

2. Claims 1-5, 8, 15-20 and 37-40 are pending.

Claims 1-5, 8, 15-20 and 37-40 are rejected.

Any rejection which is not reiterated in this action is hereby withdrawn as no longer applicable.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-5, 8, 15-20, 39 and 40 are rejected under 35 U.S.C. 102(a) as being anticipated by Alizadeh et al (Nature (February 2000) 403:503-511).

Alizadeh et al teach a method of classifying a sample according to lymphoma type (see page 504, column 2, where "the algorithm segregated, with few exceptions, the recognized classes of lymphoid malignancies") comprising:

(a) determining a gene expression profile of gene expression products from two or more informative genes, wherein the gene expression product is isolated from one or more cells in the sample (see figure 1, where Alizadeh shows screening of the microarray with mRNA sample),

wherein the gene expression profile is correlated with a lymphoma type, thereby classifying the sample with respect to lymphoma type (see figure 1 and page 505, where Alizadeh demonstrates lymphoma type association with different gene expression profiles).

With respect to claims 2, 16-17, Alizadeh expressly teaches both diffuse large-cell lymphoma and follicular lymphoma (see page 504, column 1).

With respect to claims 3 and 18, Alizadeh teaches the use of mRNA pools to form the cDNA probes (see figure 1).

With respect to claims 3 and 19, Alizadeh teaches analysis of thousands of different cDNAs for the analysis (see figure 1).

With regard to claims 5 and 20, the cDNA microarray of Alizadeh (see figure 1) is comprised of cDNA which is an oligomer of nucleotides, thereby comprising an oligonucleotide.

With regard to claims 37-40, Alizadeh teaches the use of more than 10 informative genes (see figures 1-4).

Finally, with regard to claims 1 and 8, Alizadeh expressly teaches a correlation of gene expression profile with treatment outcome, including survival as shown in figure 5 and page 509, columns 1 and 2.

Art Unit: 1637

5. Claims 1-5, 8, 15-20, 39 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Alizadeh et al (Cold Spring Harbor Symposium Quantitative Biology (June 1999) 64:71-78).

Alizadeh et al teach a method of classifying a sample according to lymphoma type (see page 76, last paragraph of column 1 to column 2, where Alizadeh discusses "We have investigated whether Lymphochip gene expression analysis can subdivide a single diagnostic category into subtypes with distinct gene expression signatures") comprising:

(a) determining a gene expression profile of gene expression products from two or more informative genes, wherein the gene expression product is isolated from one or more cells in the sample (see figure 1 and page 76, column 2, where Alizadeh states that 13 large cell lymphoma samples were screened on the Lymphochip, which is shown in Table 4 to have 12,429 different, informative genes and where the samples are drawn from one or more cells),

wherein the gene expression profile is correlated with a lymphoma type, thereby classifying the sample with respect to lymphoma type (see page 77, column 1, where Alizadeh states "Preliminary experiments with other lymphoid malignancies have show that it is possible to define sets of genes that are pathogenomic for diffuse large-cell lymphoma, follicular lymphoma and chronic lymphocytic leukemia." This statement demonstrates classification of samples to at least three different lymphoma types).

With respect to claims 2, 16-17, Alizadeh expressly teaches both diffuse large-cell lymphoma and follicular lymphoma (see page 77, column 1).

With respect to claims 3 and 18, Alizadeh teaches the use of mRNA pools to form the cDNA probes (see page 75, column 1).

With respect to claims 3 and 19, Alizadeh teaches analysis of 12,692 different cDNAs for the analysis (see page 75, table 4).

With regard to claims 5 and 20, the cDNA microarray of Alizadeh (see table 4) is comprised of cDNA which is an oligomer of nucleotides, thereby comprising an oligonucleotide.

With regard to claims 37-40, Alizadeh teaches the use of more than 10 informative genes (see table 4 with more than 12,000 genes, figure 2, and page 76, column 2, where 29 control genes were used).

Alizadeh further teaches, with regard to claims 1 and 8, that "It may be possible to use gene expression profiles to predict whether a patient is likely to fail a particular treatment regimen. Such patients could be shifted to alternative protocols that might be tailored to the biological potential of the malignant cell, as revealed by genome-wide knowledge of gene expression (see page 77, column 1)."

Finally, with regard to claim 1, each of the three lymphomas classified by Alizadeh, diffuse large-cell lymphoma, follicular lymphoma and chronic lymphocytic leukemia, have different expected treatment outcomes and therefore, the determination by Alizadeh of lymphoma type inherently is correlated with a treatment outcome, since the different lymphomas have different treatment outcomes including different survival rates as per claim 8.

Art Unit: 1637

6. Claims 1-5,8,15-20 and 37-40 are rejected under 35 U.S.C. 102(e) as being anticipated by Golub et al (1756,647,341 Nov. 11, 2003).

Golub et al teach a method of classifying a lymphoma by determining a gene expression profile of gene expression products from two or more informative genes wherein gene expression products are isolated from one or more cells (see whole doc. esp. col.2 line 31 & col. 4 line 45-50) and wherein the gene expression profile is correlated with treatment outcome thereby classifying sample with treatment outcome (see col. 8 line line 15-24).

Response to Amendment

The Declaration under 37 CFR 1.132 filed January 10, 2005 is insufficient to overcome the rejection of the claims based upon the Golub reference in 35 U.S.C. 103 as set forth in the last Office action because: The declaration is not signed.

Response to Arguments

7. Applicant's arguments filed January 10, 2005 have been fully considered but they are not persuasive.

The declaration is not signed, so it cannot overcome the Golub rejection. The new rejection is, of course, not addressed by Applicant and will presumably be addressed in a future response.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The Pedersen et al PG/Pub document, 2002/0164576 has a

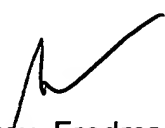
Art Unit: 1637

generic disclosure that is less complete than Alizadeh at page 18, paragraph 0209 of the specification.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is (571)272-0742. The examiner can normally be reached on 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571)272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Jeffrey Fredman
Primary Examiner
Art Unit 1637
2/16/05